

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Carl J. WHEELER

Appl. No.: 10/748,853

Filed: December 30, 2003

For: Complex Cationic Lipids Having Quaternary Nitrogens Therein Confirmation No.: 6433

Art Unit: 1614

Examiner: ROYDS, Leslie A.

Atty. Docket: 1530.0260002/JMC/OAL

## Reply to Notice of Non-Responsive Amendment

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Dear Madam:

In reply to the Office Action dated September 20, 2007, requesting a reiteration of the group selected for examination in the above-referenced patent application, Applicant hereby confirms the election to prosecute the invention of Group I (claims 64-70 and 83-86), and elect DMRIE carboxylate propyl amide as the single-disclosed species. This election is made without prejudice to or disclaimer of the other claims or inventions disclosed. This election is made with traverse.

Claims 64, 67-70, and 86 read on the elected species. Note that the invention of Group 2, especially claims 71-74 and 87, also read on the elected species. Since both Group I and Group II read on the elected species, Applicant respectfully requests that Group I and Group II be examined together.

The Office has requested a clarification of the single disclosed species of DMRIE compound elected for examination on the merits. The Examiner has indicated in the Office Action mailed on February 23, 2007 that the Office's interpretation of "DMRIE" is different than Applicant's, and the species do not include -C(O)- in the R1 and R2

radicals. In the Reply to this Restriction Requirement mailed April 4 2007, Applicant specified that the selected DMRIE carboxylate propyl amide species are exemplified in Example 3 and include -C(O)- linkage in the R1 and R2 radicals. Applicant mistakenly indicated a presence of -C(O)- in the R1 and R2 radicals of the compounds described in Example 3, and agrees with the Examiner's interpretation of the DMRIE carboxylate propyl amide species of Example 3 as having the following structure:

$$H_2C$$
 —  $O$  —  $(CH_2)_{13}CH_3$    
 $HC$  —  $O$  —  $(CH_2)_{13}CH_3$    
 $CH_3$   $O$    
 $H_2C$  —  $N$  —  $CH_2$  —  $C$  —  $NH$  —  $Propyl$    
 $CH_3$ 

Applicant apologizes for the mistaken identification of the DMRIE carboxylate propyl amide.

Second, the Office has alleged that Example 3 is "directed to multiple DMRIE species, i.e. DMRIE-Ox propyl amide, DMRIE carboxylate (methionine-methyl ester) amide, DMRIE carboxylate (methionine-leucine-methyl ester) amide, and DMRIE carboxylate (methionine-leucine-phenyl-alanine-methylester) amide," and therefore Applicants' election of the DMRIE carboxylate propyl amide species "as exemplified in Example 3 is non-compliant." In order to clarify the record, Applicant notes that DMRIE-Ox propyl amide is synonymous with the DMRIE carboxylate propyl amide, which is described as one of the four compounds in Example 3. On the contrary, DMRIE carboxylate (methionine-methyl ester) amide, DMRIE carboxylate (methionine-methyl ester) amide, DMRIE carboxylate (methionine-methyl ester) amide, DMRIE carboxylate (methionine-methyl ester)

leucine-methyl ester) amide, and DMRIE carboxylate (methionine-leucine-phenylalanine-methylester) amide are exemplified in Examples 3A-3C, respectively, and are prepared "in a similar procedure by substitution of the corresponding amines for propyl amine in the protocol of Example 3."

Reconsideration and withdrawal of the Restriction Requirement, and consideration and allowance of all pending claims, are respectfully requested.

If the Examiner believes that a telephone conference would expedite prosecution of the above-identified application, the Examiner is invited to contact the undersigned at 202-772-8673.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefore are hereby authorized to be charged to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

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Date: Mar. 18, 2008

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